

Remarks

The claims have been amended as indicated above. The amendments are being made to clarify the invention. The amendments are fully supported by the specification, claims, and figures as originally filed. No new matter is believed or intended to be involved.

The undersigned appreciate the courtesies extended by the Examiner in the telephone interview on 12/08/05. While no agreement was reached, the undersigned believes the discussion was very productive and helpful.

As an initial housekeeping matter, the Office Action did not include initialed copies of the Supplemental IDS's filed on 06/04/04 and 02/03/05. Applicants would appreciate a confirmation that the Examiner considered those listed references. Please call the undersigned if the Examiner does not have copies of these Supplemental IDS's.

The Office Action rejected claim 1 under 35 U.S.C. § 112, ¶ 2. Applicants traverse the rejection because the tube wall can be operative to separate digestive secretions from the food in the intestine. See specification at p.7, ln.30 – p.8, ln.6. Nevertheless, claim 1 has been amended to remove the cited language. Accordingly, reconsideration is requested.

The Office Action rejected claim 1-8 and 10-19 under 35 U.S.C. § 102(e) as being anticipated by two published patent applications of Levine (2004/0249362 and 2004/0220682). Attached is a declaration under 37 C.F.R. § 1.131 swearing behind the Levine applications, thus eliminating Levine as prior art. Accordingly, Applicants traverse the rejection and request reconsideration.

While the 131 declaration eliminates Levine as prior art, please note that the present application was filed before the Levine non-provisional applications were filed but after the claimed priority date to the Levine provisional applications. As such, the

Levine non-provisional applications could qualify as prior art under 35 U.S.C. § 102(e) only to the extent written support exists in the respective provisional applications. Applicants reserve all rights and arguments, accordingly.

The Office Action rejected claim 1-19 under 35 U.S.C. § 102(b) as being anticipated by Ryan (6,576,009). Applicants traverse the rejection because all of the limitations currently claimed are not taught or suggested in Ryan. Accordingly, Applicants request reconsideration.

Ryan discloses an endovascular prostheses for the treatment of diseases of the vasculature, particularly aneurysms, stenoses, and the like. (8:20-22). The dictionary defines a prostheses as “an artificial device used to replace a missing body part.” None of the present claims are directed to a prostheses, the apparatus disclosed in Ryan. Instead, the preambles make clear the currently pending claims are directed to different apparatuses and structures. For instance, claim 1 recites an “apparatus for diverting digestive secretions”; claim 14 recites an “apparatus to facilitate nutritional malabsorption”; and claim 26 recites a “diversionary tube adapted for insertion in the alimentary tract”. Applicants submit that the preamble language provides structural distinctions over Ryan.

To the extent the Office construes the preambles as reciting intended uses, the MPEP states that “a preamble may provide context for claim construction, particularly, where . . . that preamble’s statement of intended use forms the basis for distinguishing the prior art in the patent’s prosecution history.” MPEP 2111.02(II) citing *Metabolite Labs v. Corp. of Am. Holdings*, 379 F.3d 1354, 1358-62 (Fed. Cir. 2004). See also MPEP 2111.02(II) citing *Catalina Mktg. v. Coolsavings.com*, 289 F.3d 808-09 (“preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant.”) Applicants hereby rely on the preamble language to distinguish over Ryan. Plainly, Ryan does not disclose the intended uses or benefits recited in the claim preambles.

Regarding independent claim 1, the claim currently recites structural features not found in Ryan. For instance, claim 1 currently recites “an anchor adapted to be positioned in the duodenum adjacent the major duodenal papilla, said anchor being further adapted to define an annulus between the anchor and the duodenum wall when positioned in the duodenum”. As a further example, claim 1 currently recites “a tube comprising a proximal end in fluid communication with the annulus and being operative to receive digestive secretions discharged from the major duodenal papilla into the annulus.” Applicants are unaware of Ryan (or any other prior art of record) teaching or suggesting these claimed structural features. As such, claim 1 should be in a condition for allowance.

Applicants further note that claim 14 also requires the following limitation:

whereby when deployed the passage is operative to transfer the digestive secretions from the proximal end to the distal end and said tube wall separates the digestive secretions from food in the small intestine.

It is improper to disregard this limitation when evaluating the claim over the prior art. *Pac-Tec v. Amerace*, 903 F.2d 796, 801 (Fed. Cir. 1990) (For 102(a) and (b) anticipation, it was improper to delete the preamble and all limitations that include “adapted to”, “whereby”, and “thereby” so the claims are reduced to a mere collection of parts.) Ryan fails to teach this limitation. Thus, this limitation provides another reason claim 1 is patentable over Ryan.

Claims 35-37 should also be in a condition for allowance by depending from claim 1. Applicants note, however, that the dependent claims recite further limitations that distinguish over Ryan. Consider, for instance, claim 37 that further limits the anchor in claim 1 as follows: “lined stent is generally hourglass-shaped.”

Independent claim 14 currently recites structural features not found in Ryan. Ryan discloses a prostheses that will generally be radially expandable from a narrow-diameter configuration to facilitate introduction into the body lumen. Ryan sometimes

refers to the prostheses as a “stent-graft.” Ryan states the following regarding the structure of the prostheses:

An exemplary cylindrical graft structure 10 is illustrated in FIG. 1. Prosthesis 10 comprises a perforate tubular frame 12 which includes a plurality of independent (non-connected) ring frames 14. The tubular frame 12 supports an inner liner 18. Optionally, an outer liner is disposed over the ring frames, either instead of inner liner 18, or in combination therewith. (8:32-38)

Thus, Ryan discloses a prosthesis made from a lined stent, where the liner and the stent are coextensive for the entire length of the prostheses. In contrast, claim 14 currently recites an “expanding stent” and “an elongate tube extending distally beyond the expanding stent.” Accordingly, as currently recited in the claim, the elongate tube and the expanding stent cannot be coextensive for the entire length of the tube. Accordingly, claim 14 is patentable over Ryan.

Applicants further note that claim 14 also requires the following limitation:

whereby when deployed in a patient the stent is positioned in the anatomical lumen, a substantial portion of the tube is positioned in the small intestine, and the digestive secretions of the patient enter the proximal end, flow through the passage and discharge from the distal end into the intestine thereby reducing digestive contact between the digestive secretions and food in the intestine.

It is improper to disregard this limitation when evaluating the claim over the prior art. *Pac-Tec v. Amerace*, 903 F.2d 796, 801 (Fed. Cir. 1990) (For 102(a) and (b) anticipation, it was improper to delete the preamble and all limitations that include “adapted to”, “whereby”, and “thereby” so the claims are reduced to a mere collection of parts.) Ryan fails to teach this limitation. Thus, this limitation provides another reason claim 14 is patentable over Ryan.

Claims 11-13, 16-17, and 38-43 should also be in a condition for allowance by depending from claim 14. Applicants note, however, that the dependent claims recite further limitations that distinguish over Ryan.

Consider, for instance, the following dependent claims: claim 12 further recites “wherein the tube wall is at least partially permeable to water”; claim 13 further recites “wherein the tube wall has an osmotic gradient”; claim 43 further recites “wherein the tube wall is semi-permeable to digestive secretions.” The Office Action asserts Ryan discloses these characteristics without providing pin-point citations. Applicants were unable to find such teachings in Ryan, and therefore request clarification or reconsideration.

Also consider the following dependent claims: claim 16 further recites “wherein the tube is a sufficient length so that when deployed the distal end of the tube is positioned in the jejunum”; and claim 17 further recites “wherein the tube is a sufficient length so that when deployed the distal end of the tube is positioned in the ileum”; claim 44 further recites “wherein the tube wall is biodegradable.” Applicants were unable to find such teachings in Ryan, and therefore request clarification or reconsideration.

Regarding independent claim 26, the claim currently requires a “diversionary tube adapted for insertion in the alimentary tract thereby facilitating nutritional malabsorption”, and further requires the diversionary tube include “a proximal end dimensioned to be positioned in the duodenal papilla and adapted to engage the hepatopancreatic ampulla, the bile duct, or the pancreatic duct.” These are structural limitations. Indeed, the MPEP recognizes that claim language such as “members adapted to be positioned” serve to precisely define structural attributes. MPEP 2173.05(g) citing *In re Venezia*, 530 F.2d 956 (CCPA 1976) (holding “adapted to be fitted” and “adapted to be affixed” and “adapted to be positioned” imparts structural limitations.) See also *Pac-Tec v. Amerace*, 903 F.2d 796, 801 (Fed. Cir. 1990) (For 102(a) and (b) anticipation, it was improper to delete the preamble and all limitations that include “adapted to”, “whereby”, and “thereby” so the claims are reduced to a mere collection of parts.) Applicants respectfully submit that no such teaching or suggestion of these structural features are found in the prior art of record. As such, claim 26 should be allowable. Dependent claims 27-34 should likewise be allowable.

Based on the foregoing, Applicants submit that all pending claims overcome the rejections presented in the Office Action, and respectfully request reconsideration and an early notice of allowance.

Respectfully Submitted,



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